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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DECLoux, AMY M

#16

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/19/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/624,885

Applicant(s)

EDGE, ALBERT

Examiner

Amy M. DeCloux

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2002 and 26 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-15, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-15 and 18 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

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DETAILED ACTION

Applicant's amendments filed 8-16-02 and 4-26-02 (Paper Nos. 13 and 9, respectively) are acknowledged and have been entered.

Applicant's petition to include color figures under 37 C.F.R. 1.84(a)(2) is hereby accepted.

In view of Applicant's amendments, all outstanding rejections have been withdrawn. However, a new ground of rejection has been applied in this non-final office action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen et al. (1991) (J. Cell Physiology 149:525-535).

Allen et al teach a composition of skeletal muscle satellite cells which, when cultured in media with serum for 1 day contained up to 5% fibroblasts, and up to 15 % fibroblasts in cultures that were cultured from 10-20 days (about 7 to 14 days as recited in claims 8-9), said time frames of 1 day and 7-14 days encompassing 5-10 doublings as encompassed by claims 10-13 (see entire article, including the Abstract and page 526). Regarding Claims 14-15, intended use of a product is not given patentable weight in a product claim. Claims 6 and 7 are included because the composition taught by Allen et al. is the same as the recited composition comprising isolated skeletal cells and isolated fibroblast cells, regardless of how the culture is subsequently cultured. Therefore, the referenced article anticipates the claimed invention. It is noted that the specification discloses that "skeletal myoblasts" includes satellite cells, see page 5, lines 20-22 of the instant specification.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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A) Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 7 is not supported by the specification or by the claims as originally filed. There is no support in the specification or claims as originally filed for the recitation of the limitation "wherein the composition is cultured in vitro on a surface coated with collagen in a medium comprising EGF" in lines 4-5 of claim 7.

It is noted that both Example 4 and lines 8-9 of page 11 of the specification both refer to a surface coated with collagen in a medium comprising **FGF**, **not EGF**. There is no written description of the claimed invention in the specification or claims as originally filed. Thus the claimed invention constitutes new matter.

B) Claim 18 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition comprising the GATA transcription factors of GATA4 and GATA6, does not reasonably provide enablement for any GATA transcription factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant claim is drawn to a composition comprising isolated skeletal myoblasts and isolated fibroblast cells, wherein the skeletal myoblast cells are engineered to express a GATA transcription factor.

The specification discloses a composition comprising isolated skeletal myoblasts and isolated fibroblast cells, wherein the skeletal myoblast cells are engineered to express the GATA-4 or GATA-6 transcription factors, but no other GATA transcription factors.

Grepin et al. (IDS) teach that GATA4 accelerates cardiogenesis in P19 embryonic cells, and that GATA-6 could fully compensate for GATA-4 (see entire article, including the Abstract, the first paragraph of the Discussion section and the first full paragraph of column 2 of page 2393). However, GATA transcription factors are diverse in function as indicated by Weigel et al.'s teaching in US Patent 6, 107, 034, that the GATA family of transcription factors which are zinc finger transcription factors which vary with respect to function, as evidenced by GATA-3's being expressed in T cells and by ability to participate in T-cell receptor gene activation, and its unrelatedness to GATA-1, (see entire patent, especially column 2, lines 9-30).

Given the diversity of GATA transcription factors taught in the art, it would take undue experimentation by one of skill to predict which GATA transcription factors, other than GATA-4 and GATA-6, would be effective in a composition of transfected skeletal myoblasts for the disclosed utility of cardiac transplantation, without further guidance and direction from the instant specification.

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In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claim, it would take undue trials and errors to practice the claimed invention.

Allowable Subject Matter


Claim 19 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 305-3014 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.
Patent Examiner, 1644
December 2, 2002


CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
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